NDA 20-263/S-017

TAP Pharmaceutical Products, Inc.
Attention: Jessie Lee, Ph.D.
Senior Regulatory Projects Manager
675 North Field Drive
Lake Forest, IL 60045

Dear Dr. Lee:

Please refer to your supplemental new drug application dated February 6, 2001, received February 7, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lupron PED (leuprolide acetate for depot suspension) 7.5 mg, 11.25 mg, and 15 mg.

This "Changes Being Effected" supplemental new drug application provides for revision of the storage conditions in the package insert and carton labels as per ICH guidelines and deletes references to another presentation (a single dose vial with ampule of diluent) that is not currently marketed.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and carton labels submitted February 6, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Crystal King, P.D., M.G.A., Regulatory Project Manager, at (301) 827-6423.

Sincerely,

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research